



California State Board of Pharmacy

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STATE AND CONSUMERS SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN, JR.

Legislation and Regulation Committee

Kenneth Schell, PharmD, Chair

Rosalyn Hackworth, Public Member

Greg Lippe, Public Member

Shirley Wheat, Public Member

Tappan Zee, Public Member

The Legislation and Regulation Committee has not met in the last Quarter.

LEGISLATION AND REGULATION COMMITTEE

PART 3: SECOND QUARTERLY REPORT ON THE COMMITTEE'S GOALS FOR 2010/11

Attachment 1

The attached Strategic Plan goals have been modified to reflect changes during the 2nd Quarter (2010/2011).

Staff recommends the following amendments to the Strategic Plan to reflect actions of the board in previous quarters:

Objective 3.1. Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.

Objective 3.2. Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board's mission.

Task 17 - Update Protocol for Pharmacists Furnishing Emergency Contraception (ED) (§1746)

Staff recommendation to move 3.2 – Task 17 to Objective 3.3., as the board is participating with the Medical Board in a full review of the EC protocol, and modifications will need to first be approved by the Medical Board prior to consideration and possible adoption by the board.

Objective 3.3 Review five areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2011.

Task 1 – Initiate review of PIC Requirement

Task 2 – **Staff recommendation** to include Task 17 from Objective 3.2.

Task 3 – **Staff recommendation** to add "Review of Continuing Education for Pharmacists in Specific Areas"

Attachment 1

LEGISLATION AND REGULATION COMMITTEE

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Outcome: Improve the health and safety of Californians.

Objective 3.1	Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.
Measure:	100 percent successful enactment of promoted legislative changes.
Tasks:	<p>1. Secure extension of board's sunset date.</p> <p><i>1st Qtr 06/07: Governor signs SB 1476 which delays the board's sunset date two years (until 2010), and requires the board's sunset report in 2008.</i></p> <p><i>4th Qtr 06/07: SB 963 (Ridley-Thomas) is amended to alter the sunset review process.</i></p> <p><i>1st Qtr 08/09: SB 963 (Ridley-Thomas) is amended to alter the sunset review process. Board staff attend a stakeholders meeting with committee staff to discuss amendments.</i></p> <p><i>Governor signs SB 963 (Chapter 385, Statutes of 2008)</i></p> <p><i>1st Qtr 09/10: Sunset extension amended into AB 1071. Bill enrolled and sent to Governor.</i></p> <p><i>2nd Qtr 09/10: Governor signs AB 1071 (Chapter 270, Statutes of 2009) to extend the board's sunset date to 2013.</i></p> <p><i>3rd Qtr 09/10: Sunset bills introduced</i></p> <p><i>AB 1659 (Huber) – State Government, Agency Repeals</i></p> <p><i>AB 2130 (Huber) – Joint Committee on Boards, Commissions and Consumer Protection</i></p> <p><i>SB 954 (Harmon) – Legislative Procedure, Committee Referrals</i></p> <p><i>SB 1171 (Negrete McLeod) – Regulatory Boards, Operations</i></p> <p><i>4th Qtr 09/10: SB 954 (Harmon) – Bill is dead (Failed deadline)</i></p> <p><i>SB 1171 (Negrete McLeod) – Bill is dead (Failed deadline)</i></p> <p><i>1st Qtr 10/11: Governor signs AB 1659 (Chapter 666, Statutes of 2010)</i></p> <p><i>Governor signs AB 2130 (Chapter 670, Statutes of 2010)</i></p>

2. Sponsor legislation to update pharmacy law.

Enacted - 1st Qtr. 08/09: SB 1048 (Chapter 588, Statutes 2007) containing board omnibus provisions

Oct. 2007: Board sponsors omnibus provisions for 2008. Four types of changes are discussed.

(1) Changes specific to the PIC and DRC requirements

- Section 4022.5 – Designated Representative; Designated Representative-in-Charge
- Section 4036.5 – Pharmacist-in-Charge
- Section 4161 – Nonresident wholesaler
- Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action
- Section 4329 – Nonpharmacists; Prohibited Acts
- Section 4330 – Proprietors; Prohibited Acts

(2) Changes to allow for the use of mobile pharmacies

- Section 4062 – Furnishing Dangerous Drugs During an Emergency.
- Section 4110 – License Required, Temporary Permit Upon Transfer of Ownership.

(3) General changes

- Section 4059.5 – Who May order Dangerous Drugs or Devices, Exceptions.
- Section 4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory
- Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy.
- Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee.
- H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature.

(4) Changes based on recodification of Business and Professions

Code section 4052

- Section 733 – Dispensing Prescription Drugs and Devices
- Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities
- Section 4040 – Prescription; Content Requirements
- Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist
- Section 4060 – Controlled Substance – Prescription Required, Exceptions
- Section 4076 – Prescription Container – Requirements for Labeling
- Section 4111 – Restrictions on Prescriber Ownership
- Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner
- H&SC 11150 – Persons Authorized to Write or Issue a Prescription

	<p>Jan. 2008: <i>Staff provides language to Senate Business and Professions Committee for inclusion in omnibus bill SB 1779.</i></p> <p><i>Board approved language for omnibus bill.</i></p> <p>April 2008: <i>Some provisions of omnibus bill removed:</i></p> <ul style="list-style-type: none"> • <i>Section 4101 – Pharmacist-in-Charge; Designated Representative-in-Charge; Termination of Status; Duty to Notify the Board.</i> • <i>Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications</i> • <i>Section 4160 – Wholesaler Licenses</i> • <i>Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked</i> • <i>Section 4362 – Entry Into Pharmacists Recovery Program.</i> <p>Oct. 2008: <i>Governor vetoes SB 1779</i></p> <p>1st Qtr 08/09: <i>Board seeks to pursue omnibus provisions (formerly contained in SB 1779). Four areas of change: (Included in SB 819)</i></p> <p><i>(1) Changes specific to the PIC and DRC requirements</i></p> <ul style="list-style-type: none"> • <i>Section 4022.5 – Designated Representative; Designated Representative-in-Charge</i> • <i>Section 4036.5 – Pharmacist-in-Charge</i> • <i>Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action</i> • <i>Section 4329 – Nonpharmacists; Prohibited Acts</i> • <i>Section 4330 – Proprietors; Prohibited Acts</i> <p><i>(2) Changes to allow for the use of mobile pharmacies</i></p> <ul style="list-style-type: none"> • <i>Section 4062 – Furnishing Dangerous Drugs During an Emergency.</i> • <i>Section 4110 – License Required, Temporary Permit Upon Transfer of Ownership.</i> <p><i>(3) General changes</i></p> <ul style="list-style-type: none"> • <i>Section 4059.5 – Who May order Dangerous Drugs or Devices, Exceptions.</i> • <i>Section 4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory</i> • <i>Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy.</i> • <i>Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee.</i> <p><i>H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature.</i></p>
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	<p>(4) <i>Changes based on recodification of Business and Professions Code section 4052</i></p> <ul style="list-style-type: none"> • <i>Section 733 – Dispensing Prescription Drugs and Devices</i> • <i>Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities</i> • <i>Section 4040 – Prescription; Content Requirements</i> • <i>Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist</i> • <i>Section 4060 – Controlled Substance – Prescription Required, Exceptions</i> • <i>Section 4076 – Prescription Container – Requirements for Labeling</i> • <i>Section 4111 – Restrictions on Prescriber Ownership</i> • <i>Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner</i> • <i>H&SC 11150 – Persons Authorized to Write or Issue a Prescription</i> <p>1st Qtr 08/09: <i>Board seeks to introduce additional changes: (Included in SB 821)</i></p> <ul style="list-style-type: none"> • <i>Section 4101 – Pharmacist-in-Charge; Designated Representative-in-Charge; Termination of Status; Duty to Notify the board.</i> • <i>Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications</i> • <i>Section 4160 – Wholesaler Licenses</i> • <i>Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked</i> • <i>Section 4362 – Entry Into Pharmacists Recovery Program.</i> <p><i>New Provisions</i></p> <ul style="list-style-type: none"> • <i>4200.1 – Pharmacist Examination; Remedial Education</i> • <i>4112 – Non-resident Pharmacy: Registration Required</i> • <i>4146 – Return and Disposal of Sharps</i> • <i>4013 – Subscriber Alert</i> <p>3rd Qtr 08/09: <i>SB 821 introduced</i></p>
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2nd Qtr 09/10: Governor signs SB 819 and SB 821, which contains all omnibus provisions with the exception of 4200.1 - Pharmacists Examination.

3rd Qtr 09/10: Staff provides language to Senate Business Professions and Economic Development Committee for inclusion in two omnibus bills.

Omnibus Proposal #1:

- (1) Amendments to update references to the California Department of Public Health (formerly known as Department of Health Services)
 - §4017 – Authorized Officers of the Law
 - §4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities
 - §4028 – Definition of Licensed Hospital
 - §4037 – Definition of Pharmacy
 - §4052.3 – Emergency Contraception Drug Therapy; Requirements and Limitations
 - §4072 – Oral or Electronic Transmission of Prescription – Health Care Facility
 - §4101 – Pharmacist-in-Charge, Designated Representative-in-Charge; Termination of Status; Duty to Notify the Board
Prescription: Exceptions.
 - §4119 – Furnish Prescription Drug to Licensed Health Care Facility – Secured Emergency Supplies
 - §4127.1 – License to Compound Injectable Sterile Drug Products Required
 - §4169 – Prohibited Acts (also, strike operative date of 2008)
 - §4181 – License Requirements; Policies and Procedures; Who May Dispense
 - §4191 – Compliance with California Department of Public Health Requirements; Who May dispense Drugs
- (2) Amendment to update a reference to the Physical Therapy Board of California (formerly known as the Physical Therapy Examining Committee of California)
 - §4059 – Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions
- (3) Amendments to update references to the State Department of Health Care Services (formerly known as the Department of Health Services)
 - §4425 – Pharmacy Participation in Medi-Cal Program; Conditions; Department of Health Care Services Utilization Review and Monitoring
 - §4426 – Department of Health Care Services to Study Reimbursement Rates

Omnibus Proposal #2

- (1) Amend §4196(e) – Veterinary Food-Animal Drug Retailer; Designated Representative-in-Charge
- (2) Amend §4200.1 – Retaking Examinations; Limits; Requirements (NAPLEX and CPJE 4x Failure)
- (3) Add §4362 – Pharmacists Recovery Program

3rd Qtr 09/10: SB 1489 introduced (Senate Business, Professions, and Economic Development Committee). Includes proposals #1 and #2, with the exception of §4362.

	<p>4th Qtr 09/10: Board establishes support position of SB 1489. SB 1489 is amended to modify §4013 – Subscriber Alert provisions for an owner of two or more pharmacies. SB 1489 is amended to modify §4076.5 – Patient-Centered Prescription Labels to authorize the board to exempt long-term health care facilities from regulations.</p> <p>1st Qtr 10/11: Governor signs SB 1489 (Chapter 653, Statutes of 2010).</p> <p>4th Qtr 09/10: Board seeks to pursue omnibus provisions Section 4200 – Remove obsolete reference to prior pharmacist examination Staff provides language to Senate Committee on Business, Professions and Economic Development for inclusion in an omnibus bill.</p> <p>3. Advocate the board’s role and its positions regarding pharmacists’ care and dispensing of dangerous drugs and devices (AB 2408). Sep. 30, 2006: Governor signs AB 2408. Amendments taken in August remove provisions that would have described the professional services provided by pharmacists, and authorized pharmacists outside California to provide pharmacists’ care services to patients in California if licensed here or working within the framework of a nonresident pharmacy. Remaining provisions restructure pharmacist protocol provisions and several other changes.</p> <p>4. Secure statutory standards for pharmacies that compound medications (AB 595). Aug. 2006: Amendments made to remove opposition of DHS regarding pharmacy contracting with another pharmacy for compounded drugs triggers opposition from pharmacy organizations. Board drops AB 595, but will advance regulations developed for compounding pharmacies in the future. Aug. 2008: Regulatory effort initiated. (See Objective 3.2, Task 12) Oct. 2009: Board approves regulatory language for Initial Notice. Jan. 2010: Office of Administrative Law approves regulation. July 2010: Regulation effective.</p> <p>5. Secure implementation of e-pedigrees on prescription drugs dispensed in California. Sep. 2006: Governor signs SB 1476 which contains board amendments to delay implementation of the e-pedigree requirements until 2009, or upon board action, until 2011. Amendments also require interoperability, serialization, returned drug products to retain the initiating pedigree, require notice to the board of suspected or actual counterfeiting, and continuation of the pedigree through repackaging operations. Sep. 2008: Governor signs SB 1307 which delays implementation of e-pedigree.</p>
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	<p>6. Advocate the board's position on pending legislation affecting pharmacy practice and/or the board's jurisdiction.</p> <p>Oct. 2007: Governor signs the following: <i>AB 110 (Chapter 707, Statutes of 2007) Drug Paraphernalia: Clean Needle and Syringe Exchange Projects.</i> <i>SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements.</i> <i>SB 966 (Chapter 542, Statutes of 2007) Pharmaceutical Drug Disposal.</i></p> <p> Governor vetoes the following: <i>AB 249 (Eng) Healing Arts: Settlement Agreements.</i> <i>AB 543 (Plescia) Ambulatory Surgical Centers: Licensure.</i> <i>AB 1025 (Bass) Professions and Vocations: Denial of Licensure.</i> <i>SB 615 (Oropeza) Pharmacy Technicians: Scholarship Fund.</i></p> <p>Oct. 2008: Governor signs the following: <i>AB 1394 (Chapter 431, Statutes of 2008) Counterfeit: Trademarks</i> <i>SB 963 (Chapter 385, Statutes of 2008) Regulatory Boards: Sunset Review</i></p> <p> Governor vetoes the following: <i>AB 501 (Swanson) Pharmaceutical Devices</i> <i>AB 865 (Davis) State Agencies</i> <i>AB1574 (Plescia) Surgical Clinics: Licensure</i></p> <p>Jan. 2009: <i>Legislation introduced affecting Pharmacy law:</i> (New Session) <i>AB 67 (Nava) Pharmacy Patient Protection Act of 2008. Dispensing of prescriptions, irrespective of a pharmacist's ethical, moral, or religious objections.</i> <i>SB 26 (Simitian) Home-generated pharmaceutical wastes and the disposal of devices.</i></p>
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	<p>4th Qtr 08/09: AB 418 (Emmerson) Pharmacy Technicians – Education and CE Requirements AB 484 (Eng) Licensees Not in Compliance with Judgment or Order; Enforcement; Action on a License AB 718 (Emmerson) Prescription Drugs: Electronic Transmissions – Requirement to Electronically Transmit Data by January 2012 AB 830 (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia Recognized by the Centers of Medicare and Medicaid AB 877 (Emmerson) Healing Arts; DCA Committee Analysis; Scope of Healing Arts Practice AB 931 (Fletcher) Emergency Supplies – Doses Stored in an Emergency Supplies Container AB 1310 (Hernandez) Specifies Mandatory Fields for Initial and Renewal Application Forms (Various Healing Arts Boards). Annual Transmission of Data to Health Care Workforce Clearinghouse (OSHDPD) AB 1370 (Solorio) “Best Before” Date on a Prescription Label AB 1458 (Davis) Drugs: Adverse Effects Reporting SB 26 (Simitian) Home-Generated Pharmaceutical Waste SB 43 (Alquist) Cultural and Linguistic Competency SB 238 (Calderon) Medical Information SB 341 (DeSaulnier) California Department of Public Health to Contract with UC to Evaluate the Safety and Effectiveness of Prescription Drugs SB 389 (McLeod) – FBI and State Fingerprinting Requirements for DCA Boards and Bureaus SB 484 (Wright) Ephedrine Products to Schedule V SB 638 (Negrete McLeod) DCA Regulatory Boards -- Sunset Reviews SB 762 (Aanestad) Professions and Vocations; Healing Arts AB 718 (Emmerson) Prescription Drugs: Electronic Transmissions – Requirement to Electronically Transmit Data by January 2012 AB 830 (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia Recognized by the Centers of Medicare and Medicaid AB 931 (Fletcher) Emergency Supplies – Doses Stored in an Emergency Supplies Container AB 1310 (Hernandez) Specifies Mandatory Fields for Initial and Renewal Application Forms (Various Healing Arts Boards). Annual Transmission of Data to Health Care Workforce Clearinghouse (OSHDPD) SB 389 (McLeod) – FBI and State Fingerprinting Requirements for DCA Boards and Bureaus SB 484 (Wright) Ephedrine Products to Schedule V SB 638 (Negrete McLeod) DCA Regulatory Boards -- Sunset Reviews SB 762 (Aanestad) Professions and Vocations; Healing Arts</p> <p>1st Qtr 09/10: Governor signs SB 762 (Aanestad) Professions and Vocations; Healing Arts</p> <p>2nd Qtr 09/10: Governor signs SB 819 (Omnibus) Governor vetoes SB 820 (Omnibus) Governor signs SB 821 (Omnibus) Governor signs SB 470 (Corbett) - “Purpose” Governor signs AB 1071 (Emmerson) Pharmacy Fees; Sunset Governor signs AB 931 (Fletcher) - Emergency Supplies Container Governor signs AB 830 (Cook) Drugs and Devices; references to Compendia</p>
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3rd Qtr 09/10: *Board considers new legislation*

1. *Board of Pharmacy*
 - AB 2104 (Hayashi) – California State Board of Pharmacy
 - SB 1390 (Corbett) – Prescription Container Labels
2. *Pharmacy Practice*
 - AB 1869 (Anderson) – Pharmacy (spot bill)
 - AB 1916 (Davis) – Pharmacies: Mandatory Reporting of Med Errors
3. *Sunset Review and Legislative Oversight Proposals*
 - AB 1659 (Huber) – State Government, Agency Repeals
 - AB 2130 (Huber) – Joint Committee on Boards, Commissions and Consumer Protection
 - SB 954 (Harmon) – Legislative Procedure, Committee Referrals
 - SB 1171 (Negrete McLeod) – Regulatory Boards, Operations
 - SB 1172 (Negrete McLeod) – Sunset of Diversion Program
4. *Regulation of Dangerous Drugs and Devices*
 - AB 1455 (Hill) -- Pseudoephedrine
 - AB 2548 (Block) – CURES – Prescription Drug Monitoring Program
 - SB 971 (Pavley) – Bleeding Disorders: Blood Clotting Products
 - SB 1071 (DeSaulnier) – CURES
 - SB 1106 (Yee) – Prescribers – Dispensing of Samples
5. *Pharmacy Licensing Issues*
 - AB 2077 (Solorio) – Centralized Hospital Packaging Pharmacies
 - AB 2292 (Lowenthal) – Pharmacy: Clinics
 - AB 2551 (Hernandez) – Pharmacy Technician: Scholarship and Loan Repayment Program
6. *Distribution of Needles and Syringes*
 - AB 1701 (Chesbro) – Hypodermic Needles and Syringes
 - AB 1858 (Blumenfield) – Hypodermic Needles and Syringes: Exchange Services
 - AB 2139 (Chesbro) – Solid Waste: Product Stewardship
 - SB 1029 (Yee) -- Hypodermic Needles and Syringes
7. *General / Other*
 - AB 2112 (Monning) – Prescription Record Privacy Act

	<p>4th Qtr 09/10: Board considers additional legislation AB 1939 (Fletcher) Sharps Waste SB1111 (Negrete McLeod) DCA Enforcement Model</p> <p>Apr. 2010: Board takes positions on legislative measures: AB 1701 (Chesbro) Support AB 2104 (Hayashi) Oppose AB 2292 (Lowenthal) Support SB 1106 (Yee) Support if Amended AB 1916 (Davis) Bill is dead (failed deadline) AB 2112 (Monning) Bill is dead (failed deadline) SB 1111 (Negrete McLeod) Bill is dead (failed deadline)</p> <p>May 2010: AB 1869 (Anderson) Bill is dead (failed deadline) AB 1939 (Fletcher) Bill is dead (failed deadline)</p> <p>June 2010: SB 1390 (Corbett) Fails passage in policy committee SB 954 (Harman) Bill is dead (failed deadline) SB 1171 (Negrete McLeod) Bill is dead (failed deadline) AB 2139 (Chesbro) Bill is dead (failed deadline) AB 2292 (Lowenthal) Bill is dead (failed deadline) AB 2548 (Block) Bill is dead (Failed deadline)</p> <p>Apr./May 2010: AB 2104 (Hayashi) Amended twice</p> <p>June 2010: AB 2104 (Hayashi) Amended to authorize Board appointment of Executive Officer with approval of DCA Director.</p> <p>July 2010: AB 2077 (Solorio – Centralized Hospital Packaging Pharmacies. Board establishes Support position.</p>
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1st Qtr 10/11: Governor signs the following legislation:

AB 2104 (Hayashi) – Requires DCA Director approval of the Board's appointment of Executive Officer (Chapter 374, Statutes of 2010)
AB 1659 (Huber) – State Government, Agency Repeals (Chapter 666, Statutes of 2010)

AB 2130 (Huber) – Joint Committee on Boards, Commissions and Consumer Protection (Chapter 670, Statutes of 2010)

SB 1172 (Negrete McLeod) – Diversion Programs (Chapter 517, Statutes of 2010)

AB 1071 (Chesbro) – Hypodermic Needles and Syringes (Chapter 667, Statutes of 2010)

SB 1414 (Hill) – Apomorphine: Unscheduled (Chapter 76, Statutes of 2010)

AB 2699 (Bass) – Licensure Exemption: State of Emergency (Chapter 270, Statutes of 2010)

Governor vetoes the following legislation:

AB 1858 (Blumenfield) – Hypodermic Needles and Syringes

SB 1029 (Yee) – Hypodermic Needles and Syringes

AB 2077 (Solorio) – Centralized Hospital Packaging Pharmacies

SB 971 (Pavley) – Bleeding Disorders: Blood Clotting Products

AB 2747 (Lowenthal) – Prisons: Pharmacy Services

The following legislation fails passage:

AB 1455 (Hill) – Pseudoephedrine

SB 1071 (DeSaulnier) – CURES

SB 1106 (Yee) – Prescribers Dispensing of Samples

AB 2551 (Hernandez) – Pharmacy Technician Scholarship & Loan Repayment Program

AB 1310 (Hernandez) – Healing Arts Database

2nd Qtr 10/11: SB 41 (Yee) Introduced – Hypodermic Needles and Syringes

AB 36 (Hill) Introduced – Ephedrine: Retail Sale

Board approves provisions for sponsorship in 2011/2012 Session:

(1) Pharmaceutical Waste – Reverse Distributors

- Section 4040.5 – Amend to specify that a reverse distributor may not accept previously dispensed medicine and specify that previously dispensed medicine returned to a pharmacy can only be handled by a licensed integrated waste hauler.
- Section 4081 – Amend to specify what records must be maintained of drugs being returned to a wholesaler or reverse distributor; and specify information that is to be maintained for drugs that are returned via a licensed integrated waste hauler.
- Section 4126.5 – Amend to authorize a pharmacy to furnish drugs to a licensed integrated waste hauler for the sole purpose of disposing of pharmaceutical waste returned to a pharmacy.

(2) Pharmacists Recovery Program

- Section 4362 – Amend to require that a participant in the pharmacists recovery program be responsible to pay an administrative co-pay each month to cover a portion of the administrative costs borne by the board; provision to allow the board to waive or defer the requirement based on a demonstrated financial hardship.

3rd Qtr 10/11: SB 100 (Price) Introduced – Healing Arts Licensees; Advertising; Sugical Clinics (Capen V. Shewry)

	<p>7. Expand the conditions under which a pharmacist may administer an immunization independent of physician protocol.</p> <p><i>March 2007: Licensing Committee considers and approves concept. More work is required.</i></p> <p><i>June 2007: Licensing Committee considers draft language and requests additional refinements to proposal for consideration at September 2007 committee meeting.</i></p> <p><i>Sept. 2007: Licensing Committee forwards to full board legislative proposal.</i></p> <p><i>Oct. 2007: Board approved draft legislation.</i></p> <p><i>Nov. 2007: Staff meeting with stakeholders to elicit support for the proposal.</i></p> <p><i>Dec. 2007: Staff develop fact sheets and work with experts in immunizations.</i></p> <p><i>Feb. 2009: Assembly Member Skinner authors AB 977, to allow pharmacists to initiate and administer immunizations pursuant to the Centers for Disease Control's guidelines for the adult and adolescent immunizations schedules.</i></p> <p><i>April 2009: Bill amended to allow pharmacists to initiate and administer pneumonococcal and influenza vaccines.</i></p> <p><i>May 2009: Bill amended to intent language requesting the California Pharmacists Association to provide information to legislative Committees on the status of immunization protocols. (2-year bill)</i></p> <p><i>Jan. 2010: Bill amended (removing opposition) to allow pharmacists to administer influenza vaccinations pursuant to protocol and to require specified documentation and reporting.</i></p> <p><i>Jan. 2010: AB 977 passes out of Assembly Health Committee Board reaffirms "support" position.</i></p> <p><i>April 2010: Board changes position from "sponsor" to "support".</i></p> <p><i>June 2010: AB 977 amended to apply only to a pharmacist associated with an independent community pharmacy. Bill died in committee.</i></p>
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	<p>8. Advocate the board's role as an advocate for consumers by redesigning prescription label for all medicines dispensed to California patients.</p> <p><i>Oct. 2007: Governor signs SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements.</i></p> <p><i>Apr. 2008: First public forum held in Fremont.</i></p> <p><i>May 2008: Staff develop survey form to distribute to consumers to solicit input</i> <i>Staff attend Senior Seminar, interview attendees about prescription label and distribute surveys.</i></p> <p><i>June 2008: Staff attends community events, interview attendees about prescription label and distribute surveys.</i></p> <p><i>July 2008: Staff attends community events, interview attendees about prescription label and distribute surveys.</i></p> <p><i>Oct. 2008: Staff continues to attend community events, interview attendees about prescription label and distribute surveys.</i> <i>Public Education Committee updated on the status of survey results.</i></p> <p><i>Feb. 2009: Senator Corbett authors SB 470, to allow the purpose for which a medicine is prescribed to be included in the prescription and prescription label.</i></p> <p><i>May 2009: Bill passes out of the Senate</i></p> <p><i>Oct. 2009: Governor signs SB 470 (Chapter 590, Statutes of 2009).</i></p> <p><i>Oct. 2009: Board approves regulatory language for notice.</i></p> <p><i>Nov. 2009: Regulatory effort initiated</i></p> <p><i>June 2010: Board adopts final text (See Objective 3.2, Task 16)</i></p> <p><i>Oct. 2010: Rulemaking submitted to the Office of Administrative Law for review.</i></p> <p>9. Secure statutory fee increase to ensure sufficient funding to fulfill all of the boards statutory obligations as a consumer protection agency.</p> <p><i>Dec. 2008: Board receives findings of independent fee audit.</i></p> <p><i>Jan. 2009: Board votes to pursue fee increase.</i></p> <p><i>Feb. 2009: Assembly Member Emmerson authors AB 1071 which establishes new application and renewal fees.</i></p> <p><i>June 2009: Bill passes out of the Assembly.</i></p> <p><i>Sept. 2009: Bill is enrolled and sent to the Governor.</i></p> <p><i>Sept. 2009: Bill enrolled, then pulled back and amended to include sunset provisions for the board. Amendments pass Senate and Assembly concurs. The bill is re-enrolled.</i></p> <p><i>Oct. 2009: Governor signs AB 1071 (Chapter 270, Statutes of 2009)</i></p> <p><i>Jan. 2010: Statutory fee schedule implemented (supersedes 16 CCR 1749)</i></p>
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10. Advocate legislation to enhance the board's enforcement activities.

Jan. 2010: *Staff working to include in department-wide enforcement legislation the following enhancements to the board's enforcement activities (board approved Oct 2009):*

Section 4081 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory.

Section 4104 - Licensed Employee, Theft or Impairment, Pharmacy Procedures.

Section 4112 - Nonresident Pharmacy; Registration; Provision of information to Board; Maintaining Records; Patient Consultation

2nd Qtr 10/11: *Board approves provisions for sponsorship in 2011/2012 Session:*

(1) Enforcement Enhancements

- Section 4104 – Amend to clarify that a pharmacy shall provide to the board, within 14 days, evidence of a licensee's theft or impairment. Require the pharmacy to conduct an audit to determine the scope of loss, and to provide the board with a certified copy of the audit results.*
- Section 4105 – Amend to specify a time period in which records shall be provided to the board when requested by an inspector or authorized representative of the board.*

Objective 3.2	Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board's mission.
Measure:	Percentage successful enactment of promoted regulatory changes.
Tasks:	<ol style="list-style-type: none"> 1. Authorize technicians to check technicians in inpatient pharmacies with clinical pharmacist programs (sections 1793.7-1793.8). <i>Jan. 2007: Office of Administrative Law approves rulemaking. Regulation takes effect.</i> 2. Authorize the use of prescription drop boxes and automated delivery machines for outpatient pharmacies (sections 1713 and 1717(e)). <i>Jan. 2007: Regulation takes effect following approval by the Office of Administrative Law.</i> 3. Make technical changes in pharmacy regulations to keep the code updated. <i>April 2007: Section 1775.4 – contested citations. DCA determines no regulation is needed to accomplish the requirement to allow 1 rescheduling of an office conference. This regulation is withdrawn.</i> <i>June 2007: Section 1706.2 – Criteria for abandonment of files, changes take effect following approval by the Office of Administrative Law.</i> 4. Repeal the requirement to post a notice regarding electronic files (section 1717.2). <i>March 2007: Office of Administrative Law approves rulemaking. Regulation takes effect.</i> 5. Revise and update Disciplinary Guidelines revision and update (section 1760). <i>Oct. 2007: Board approves regulation for 45-day comment period.</i> <i>May 2009: Regulation and revised Disciplinary Guidelines approved and takes effect.</i> 6. Self-assessment of a wholesaler by the designated representative (section 1784). <i>April 2007: Office of Administrative Law approves rulemaking. Regulation takes effect.</i> 7. Exempt the address of records of interns from display on the board's Website (section 1727.1). <i>Sept. 2006: Office of Administrative Law approves rulemaking. Regulation takes effect October 2006.</i> 8. Modification of building standards for pharmacies – rulemaking by the California Building Standards Commission. <i>July 2006: Board notified that a new procedure now exists for adopting building standards. Staff will pursue these procedures in 2007.</i> <i>June 2007: Board staff submit rulemaking file to the California Building Standards Commission.</i> 9. Update Notice to Consumers Poster in conformance with AB 2583 (Chapter 487, Statutes 2006)(Section 1707.2). <i>Feb. 2007: Board notices regulation for 45 days comment period.</i> <i>Nov. 2007: Regulation changes takes effect.</i> <i>Jul. 2008: Board mails updated Notice to Consumers to all pharmacies in California.</i>

	<p>10. Secure changes without regulatory effect (Section 100 changes) to pharmacy regulations to keep them accurate and current.</p> <p><i>Dec. 2007: Office of Administrative Law approves Section 100 Changes. Amend the following:</i></p> <p><i>1707 – Waiver of requirements for off-site storage of records</i></p> <p><i>1709.1 – Designation of pharmacist-in-charge</i></p> <p><i>1715 – Self-assessment of a pharmacy by the pharmacist-in-charge</i></p> <p><i>1717 – Pharmacy practice</i></p> <p><i>1746 – Emergency contraception</i></p> <p><i>1780.1 – Minimum standards for veterinary food-animal drug retailers</i></p> <p><i>1781 – Exemption certificate</i></p> <p><i>1787 – Authorization to distribute dialysis drugs and devices</i></p> <p><i>1790 – Assembling and packaging</i></p> <p><i>1793.8 – Technician check technician</i></p> <p><i>Repeal section 1786 – Exemptions</i></p> <p><i>March 2009: Office of Administrative Law approves Section 100 Changes to update the self-assessment forms required in California Code of Regulations 1715 and 1784.</i></p> <p>11. Increase fees to keep the board's contingency fund solvent and maintain operations.</p> <p><i>Nov. 2007: Office of Administrative Law approves rulemaking.</i></p> <p><i>Nov. 2007: Staff complete necessary programming changes and begin advising licensees of the change.</i></p> <p><i>Jan. 1, 2008: New fees take effect.</i></p> <p><i>Oct. 2009: Governor signs AB 1071, new fee schedule.</i></p> <p><i>Jan. 2010: Statutory fee schedule becomes effective (supersedes 16 CCR §1749)</i></p> <p>12. Secure regulatory standards for pharmacies that compound. (§1735 et al)</p> <p><i>Nov. 2007: Board releases language for the 45-day comment period.</i></p> <p><i>Sep. 2008: Board releases (withdrawn) language for 45-day comment period.</i></p> <p><i>Oct. 2008: Regulation hearing</i></p> <p><i>Jan. 2010: Office of Administrative Law approves regulation.</i></p> <p><i>July 2010: Regulation and Self-Assessment Form 17M-39 is effective. Board staff developing fact sheet for pharmacies.</i></p> <p>13. Establish an ethics course (§1773 and §1773.5).</p> <p><i>Sep. 2008: Board notices regulation for 45-day comment period.</i></p> <p><i>Sep. 2009: Regulation takes effect.</i></p> <p>14. Pharmacist Renewal Requirements (§1702).</p> <p><i>Dec. 2009: Board notices regulation for 45-day comment period.</i></p> <p><i>Feb. 2010: Board adopts regulation.</i></p> <p><i>June 2010: Office of Administrative Law approves regulation (to be effective Dec. 2010)</i></p> <p>15. Dishonest Conduct During Pharmacist Examination; Confidentiality of Exam Questions (§1721 and §1723.1).</p> <p><i>Oct. 2009: Board notices regulation for 45-day comment period.</i></p> <p><i>Jan. 2010: Board adoption of regulation as noticed.</i></p> <p><i>July 2010: Rulemaking submitted to the Office of Administrative Law for review.</i></p> <p><i>Aug. 2010: Office of Administrative Law approves regulation.</i></p> <p><i>Sep. 2010: Regulation takes effect.</i></p>
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	<p>16. Standardized, Patient-Centered Prescription Labels <i>Oct. 2009: Board approves language to initiate rulemaking.</i> <i>Nov. 2009: Board notices regulation for 45-day comment period.</i> <i>Jan. 2010: Regulation hearing.</i> <i>Feb. 2010: Board modifies text of regulation.</i> <i>Board notices modified text for 1st 15-day comment period.</i> <i>Apr. 2010: Board modifies text of regulation.</i> <i>Board notices modified text for 2nd 15-day comment period.</i> <i>June 2010: Board adopts regulation language noticed on April 28.</i> <i>July 2010: Rulemaking submitted to Department for review.</i> <i>Oct. 2010: Rulemaking submitted to the Office of Administrative Law for review.</i></p> <p>17. Update Protocol for Pharmacists Furnishing Emergency Contraception (EC) (§1746) <i>Jan. 2010: Board approves language to initiate rulemaking to correct a typographical error in the Emergency Contraception Protocol regulation.</i> <i>July 2010: Board begins working with Medical Board to update the EC Protocol.</i></p> <p>18. Board Issued Continuing Education (CE) Credit (§1732.2) <i>Feb. 2010: Board votes to amend section 1732.2 defining board-issued CE and notice regulation for 45-day comment period.</i> <i>Oct. 2010: Board notices regulation for 45-day comment period.</i></p> <p>19. Notice to Consumers re: Patient-Centered Prescription Labels <i>Apr. 2010: Board directs staff to bring regulatory language to the July 2010 meeting re: increased font size, and language services.</i> <i>July 2010: Board discusses possible language for Notice to Consumers.</i> <i>October 2010: Board discusses possible language for Notice to Consumers. Votes to modify and move existing Consumer Notices from §1702. to a new section at 16 CCR §1707.6., to include language for increased font size and oral interpretive services. Discussion to continue at next board meeting.</i></p> <p>20. Update references to USP Standards (§1780) <i>1st Qtr 07/08: Board considers review of USP references.</i> <i>2nd Qtr 07/08: Subcommittee established to conduct full review of USP updates needed.</i></p> <p>21. Veterinarian Food-Animal Drug Retailer Self-Assessment (§1785) <i>1st Qtr 07/08: Board approves regulation for notice.</i> <i>2nd Qtr 07/08: Work on rulemaking stopped to allow for comprehensive review of Veterinary Food-Animal Drug Retailer Program.</i></p> <p>22. Accreditation Agencies for Pharmacies that Compound (§1751.x) <i>1st Qtr 07/08: Board approves regulation text for notice (upon additional review by counsel, modification of language is necessary prior to notice of proposed text)</i></p>
	<p>23. Applicants to submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB)(§ 1727.2, § 1728, § 1793.5) <i>2nd Qtr 10/11: Board votes to require applicants to submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB), and to amend/update the Pharmacy Technician application:</i></p> <ul style="list-style-type: none"> <i>• Section 1728 – Amend to require an applicant for the pharmacist examination to submit a Self-Query Report from NPDB-HIPDB.</i> <i>• Section 1727.2. – Add new section to require an applicant for an Intern Pharmacist license to submit a Self-Query Report from NPDB-HIPDB.</i> <i>• Section 1793.5. – Amend to require a Pharmacy Technician applicant to submit a Self-Query Report from NPDB-HIPDB; and to modify the Pharmacist Technician Application (17A-5), incorporated by reference.</i>

Objective 3.3	Review five areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2011.
Measure:	Number of areas of pharmacy law reviewed.
Tasks:	<p>1. Initiate review of the pharmacist-in-charge requirement.</p> <p><i>Aug. 2007:</i> Staff and counsel review pharmacist-in-charge and designated representative-in-charge statutes and regulations for reporting requirements and make recommendations to amend various statutes and regulations.</p> <p><i>Oct. 2007:</i> Legislation and Regulation Committee reviews draft language to be incorporated into omnibus bill.</p> <p><i>Jan. 2008:</i> Board approves omnibus language recommended by Legislation and Regulation Committee.</p> <ul style="list-style-type: none"> • Section 4022.5 – Designated Representative; Designated Representative-in-Charge • Section 4036.5 – Pharmacist-in-Charge • Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the board. • Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications • Section 4160 – Wholesaler Licenses • Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked • Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action • Section 4329 – Nonpharmacists; Prohibited Acts • Section 4330 – Proprietors; Prohibited Acts <p><i>April 2008:</i> The following provisions are not incorporated into omnibus bill.</p> <ul style="list-style-type: none"> • Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the board. • Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications • Section 4160 – Wholesaler Licenses • Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked <p><i>Sept. 2008:</i> Governor vetoes SB 1779.</p> <p><i>Jan. 2009:</i> Board seeks to reintroduce provisions contained in SB 1779 via omnibus bill. Provisions contained in SB 819 and SB 821. Senate BP & ED introduce Omnibus bills containing previously-approved / Pharmacist-in-Charge provisions.</p> <p><i>Sept. 2009:</i> SB 819 and SB 821 enrolled and sent to the Governor.</p> <p><i>Oct. 2009:</i> Governor signs SB 819 and SB 821. Provisions go into effect January 2010.</p>